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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,964

04/21/2004

Weston F. Harding

P-5540C1

5397

26253 7590 08/04/2009
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,964	Applicant(s) HARDING ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

The Pre-Appeal Brief filed on 5/5/09 has been considered. Examiner would like to withdraw the Final Office Action mailed out 12/26/08. Since this new rejection was not necessitated by amendment, the present Office Action is made Non-Final.

Claims 32-37 are present for examination.

Claims 1-31, 38-39 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the Specification discloses the limitation: "a portion of the longitudinal slit in the distal portion of the septum is closed" under restrained by a distal portion of the channel.

According to the Specification, it states that: If desired, slit 25 can be formed so it is open when distal portion 23 is in its unstressed state", page 22, lines 13-14, and also shown in Figs. 40 and 42. The Figs. 37-39 are shown that the slit 25 is closed. But nowhere in the specification clearly mentioned or explained what shape of channel and the shape of distal portion of the septum under unstressed condition and restrained condition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Behnke et al. (US 5,354,275).

Behnke discloses a needle-less luer access connector comprising:

a housing 104, having a top portion 116 defining an inlet opening, a channel (including 110 and portion 112) defined by at least one sidewall extending from the inlet opening and having a cross section, and a bottom portion defining an outlet opening extending from the channel;

a septum 106 disposed in the housing, the septum having a proximal portion 108, a medial portion having an external surface and a cross section less than a cross section of the top portion and less than the cross section of the channel, and a distal portion (including bore portion 126 and portion 118) defining a substantially circular cross section (portion of element 118 in phantom line) in its unstressed condition (see Figs. 10 and 11);

a longitudinal slit including 128 extending through the septum from the proximal portion through the medial portion and into the distal portion; and

wherein the channel has a substantially elliptical cross section (col. 5, lines 52-54) having a major axis and a minor axis along at least a distal portion thereof and the distal portion of the septum is located in and restrained by a distal portion of the channel such that the distal portion 118 of the septum 106 is biased into a substantially elliptical shape by the distal portion of the channel and a portion of the longitudinal slit in the distal portion of the septum is closed, see Figs. 14-15.

As noted that, the distal portion 118 of septum 26 formed of circular shaped (as discussed above); while the channel (passageway 110 includes a septum-receiving portion 112) has a generally elliptical cross-section (col. 5, lines 52-55). The insertion of the septum into the housing causes the septum to compress. At this point, under restraining/compression of channel, the septum made of elastomeric material is inherently biased into a shape of channel (elliptical shape) to fit and sealed inside the septum-receiving portion 112.

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Regarding claim 33, wherein the longitudinal slit is defined by a pair of transversely extending walls of the septum which are parallel to a transverse axis of the slit and wherein the transverse axis of the slit is substantially aligned with the major axis.

Regarding claim 34, wherein the portion of the slit in the distal portion of the septum is open in the unstressed condition, Figs. 10-11.

Regarding claim 35, Behnke discloses, in Figs. 1-6 and 14, a needle-less luer access connector, comprising:

a housing 24 having a top portion defining an inlet opening, a channel 32 defined by at least one sidewall extending from the inlet opening and having a cross section, and a bottom portion defining an outlet opening extending from the channel;

a septum 26 disposed in the housing, the septum having a proximal portion 44, a medial portion having an external surface and a cross section less than a cross section of the top portion and less than the cross section of the channel 32 and; a distal portion (including bore portion 46 and 38) defining a substantially elliptical cross section (portion of 46 generally elliptical cross section, col. 4, lines 40-50) with a major axis and a minor axis in its unstressed condition;

a longitudinal slit 48 extending through the septum from the proximal portion through the medial portion and into the distal portion; and

wherein the channel 32 has a substantially circular cross section along at least a distal portion thereof (col. 3, lines 42-46) and the distal portion of the septum is located in and restrained by a distal portion of the channel. Behnke further discloses that: the bore 46 is preferably shaped so that when the septum 26 is installed in the generally circular passageway 30 of the housing 24, the septum 26 compresses in such a way that the bore 46 assumes a generally circular cross-section (col. 4, lines 46-50). In other words, under compression of channel 32 or housing 24, a distal portion 46 of septum 26 will be deformed or biased into a shape of distal portion channel 32, which is elliptical shape.

a portion of the longitudinal slit 48 in the distal portion of the septum is closed, see Fig. 14.

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Regarding claim 36, wherein the longitudinal slit is defined by a pair of transversely extending walls of the septum which are parallel to a transverse axis of the slit and wherein the transverse axis of the slit is substantially aligned with the major axis.

Regarding claim 37, wherein the portion of the slit in the distal portion of the septum is open in the unstressed condition, Figs. 1-6.

Response to Arguments

Applicant's arguments with respect to claims 32-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763